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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,902	07/02/2002	Nikolai Vladimirovich Bovin	9286-7	7167
20792	7590	04/05/2005	EXAMINER	
MYERS BIGEL SIBLEY & SAJOVEC			MAIER, LEIGH C	
PO BOX 37428			ART UNIT	
RALEIGH, NC 27627			PAPER NUMBER	

1623

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/019,902

**Applicant(s)**

BOVIN ET AL.

**Examiner**

Leigh C. Maier

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-6,8-12,14-16,18,20,23,27 and 28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-12,14-16,18,20,23,27 and 28 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 1/12/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of the Claims***

Claims 1, 12, 15, 18, 23, 17, and 28 have been amended. Claims 1-6, 8-12, 14-16, 18, 20, 23, 27, and 28 are pending. Any rejection or objection not specifically repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Drawings***

The examiner acknowledges receipt of the replacement drawing for Figure 1. This corrected drawing is found to be acceptable.

### ***Claim Rejections - 35 USC § 112 – 1<sup>st</sup> paragraph***

Claims 1-6, 8-12, 14-16, 18, 20, 23, 27, and 28 are again rejected under 35 U.S.C. 112, first paragraph as set forth in the previous Office action, because the specification, while being enabling for the examples disclosed in the specification that are described as forming aggregates and having utility in the inhibition of the influenza virus but not the full scope of compounds (limited to those wherein  $X=CH_{4-m}$  at this stage of examination) encompassed by the claims, does not reasonably provide enablement for the full scope of compounds embraced by the formula wherein  $X=CH_{4-m}$ .

Applicant's arguments filed January 10, 2005 have been fully considered but they are not persuasive.

Applicant counters the Tuzikov teaching that compounds with  $n < 6$  do not associate under particular conditions by stating that "association may and can take place under other conditions that can be determined by routine experimentation." From this, it appears that Applicant's position is that aggregation under *some set of conditions* is an inherent property of the compounds that are structurally consistent with the instant claims. Therefore, it would appear that Applicant's position is that proviso (3) of claim 1 is not actually limiting. However, at page 2 (lines 6-9) of the specification, Applicant discusses a compound disclosed in WO 98/14215. The compound is consistent with instant Formula I, but the specification states "[t]hat compound does not, however, form aggregates in aqueous solution." It is noted that the specification does not state "the reference does not recognize that this compound may be manipulated in such a way to form aggregates, thus increasing its art-disclosed utility as a virus cell adhesion inhibitor." On the other hand, if it does not form aggregates in aqueous solution, it is not clear how the benefit of aggregate formation would manifest itself *in vivo*, as claimed.

Applicant further argues different conditions of association "would be known to one of ordinary skill in the art and Applicants need only demonstrate the ability to associate in general in order to adequately enable this invention." The examiner respectfully disagrees. This might be found persuasive if the claims were drawn to a group of compounds that were more structurally similar. However, all the compounds exemplified have identical branches wherein all the branches comprise five glycines at the inner part of the branch. These compounds are not even representative of all the possible compounds having identical branches, and not remotely representative of the full complement of compounds embraced by the instant claims. The examiner reiterates the Turikov teaching that "[t]he unusual stability of the tectomer in aqueous

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media can be explained by the participation of all CO and NH glycine groups in H bonding in a highly cooperative manner. . .” See page 150, last paragraph. It appears that the glycopeptides comprising oligoglycyl (or perhaps any [amino acid]<sub>n>5</sub>) branches may be a special sub-set within the recited compounds.

Applicant notes that compounds #33-#35 are examples of compounds wherein the B moiety is not defined only by glycine. The examiner agrees. However, these compounds also have five glycines at the inner positions of the identical branches, as described above. After consideration of these compounds, cited by Applicant, the examiner notes that compounds 40-42, rather than only 42, are consistent with this formula, but are described as having “no self-association” and low activity in the assay of Table 8.

Applicant further states that tetraantennary molecules with  $k=10$  and biantennary molecules with  $k \gg 10$  have been synthesized, but there is no indication of what the structure of these compounds is. That is, are they more oligo-gly branched compounds?

Finally Applicant cites in vitro test other than the influenza assay noted in the previous Office action. This data is noted. However, data is presented for a single compound. Again, the examiner returns to the Turikov reference that teaches that non-assembling glycopeptides have no particular advantage over the monomer. Furthermore, this reference also points to the fact that the saccharide R moieties are very specific in their binding. Compare the  $\alpha$ - and  $\beta$ -forms in Table 1. The specification gives little guidance as to which R would be useful for a particular therapeutic method.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8, 18, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by BOVIN et al (WO 98/14215).

As noted above, from the response filed January 10, 2005, it appears that Applicant's position is that all compounds consistent with the recited formula has the inherent property of forming aggregates under some set of circumstances so that proviso (3) of claim 1 is not actually limiting.

BOVIN discloses a compound consistent with the structural formula of the claims. See example 7. The reference discloses that it has utility as a virus cell adhesion inhibitor for treatment of influenza. See abstract. Since the Office does not have the facilities for preparing the claimed materials and comparing them with prior art inventions, the burden is on Applicant to show a novel or unobvious difference between the claimed product and the product of the prior art. See *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

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Applicant's argument necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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*Examiner's hours, phone & fax numbers*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

*Leigh C. Maier*

Leigh C. Maier  
Primary Examiner  
March 17, 2005